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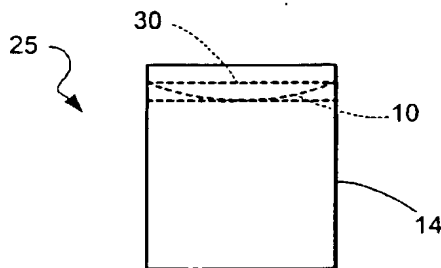
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(54) Title: **STENT WITH VALVE AND METHOD OF USE THEREOF**

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(57) Abstract: A heart valve stent (25) and method for treating a patient with a fluid circulatory system defect is provided. The stent has a metal stent body (14), which is expandable from a compressed state to an expanded state. The stent body in the expanded state has a hollow structure and a leaflet (10) attached thereto with the leaflet movable from an open to a closed position to allow unidirectional fluid circulation and to prevent non-unidirectional fluid circulation through the hollow structure, which is translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto.

STENT WITH VALVE AND METHOD OF USE THEREOF

TECHNICAL FIELD

The present invention relates to stents generally and more specifically but not exclusively to a heart valve stent and a method of using the heart valve stent.

5

BACKGROUND ART

The normal human heart is a four chamber muscular organ which serves as the main pump of blood of the circulatory system. Systemic venous blood enters the right atrium through the superior and inferior vena cavae; then through the tricuspid valve enters the right ventricle where it is pumped to the pulmonic artery and the lungs through the pulmonary valve. Blood from the lungs enters the left atrium through the four pulmonary veins; then through the mitral valve enters the left ventricle where it is pumped to the aorta and the rest of the body through the aortic valve. The function of these valves is to allow blood flow easily through them in one direction by opening the leaflets and preventing blood from regurgitating back by closing the leaflets. In some individuals, one or more valves may not function normally, usually as a result of disease-induced valve damage, degeneration or a congenital defect. Some valves may become stenotic, thus impeding forward blood flow, and some valves may become incompetent, thus allowing blood to backflow through them. Both conditions can lead to life-threatening conditions.

In one group of patients, obstruction occurs at the level of the valve itself or distal, i.e., behind the valve, in the direction of the blood flow. Replacement or repair of defective valves has been done so far only by open-heart surgeries requiring the patients to be fully anesthetized for several hours. Thoracotomy, a process in which the sternum is cut open the entire length, and connection of the patient to a heart-lung machine, is required. One associated risk is the formation of blood clots. Blood clots may go into either the brain or the extremities and cause lethal damage. About two percent of open-heart surgery patients have a risk of lethal complications. In addition to expensive medical equipment, open-heart surgery requires very sophisticated and experienced surgeons and a large number of supporting staff. Furthermore, the costs are extremely high to care for the patients and to keep the patients in the hospital for several days after surgery. Finally, some patients may suffer from sizeable scarring, which sometimes present significant cosmetic problems.

In the past, two types of replacement valves, mechanical valves and biological valves, were usually inserted by open-heart surgery. Both of these two types of the valves have advantages and disadvantages.

5 Mechanical valves have the advantage that they last for a long time. The disadvantages, however, is that it is likely that blood clotting will occur. As a result, lifelong treatment would be required, because these patients must take anti-coagulation drugs for the remainder of their lives.

Biological or bioprosthetic valves, i.e., porcine or bovine valves, have the advantage that no anti-coagulation treatments for the patients are necessary and they can be easily
10 imaged. However, the disadvantage is that the biological valves in more than fifty percent of all patients, and in a hundred percent of the patients, who are younger than thirty-five years, become dysfunctional. Consequently, these patients require open-heart surgery for a second time and subject themselves again to the expenses and the traumatic experience of further open-heart surgery.

15 A more specific problem occurs in children, who have congenital heart diseases, which is predominantly found on the right side of the heart affecting the pulmonary truncus. Obstructions in blood vessels, such as the pulmonary truncus, occur in about five to eight percent of the congenital heart disease cases. Open-heart surgery for repair has to be undertaken or an endovascular stent has to be placed to open up the blood vessels. In both
20 cases, patients' pulmonary valves would be inevitably destroyed.

In the medical field, magnetic resonance imaging (MRI) is used to non-invasively produce medical information. The patient is positioned in an aperture of a large annular magnet, and the magnet produces a strong and static magnetic field, which forces hydrogen and other chemical elements in the patient's body into alignment with the static field. A
25 series of radio frequency (RF) pulses are applied orthogonally to the static magnetic field at the resonant frequency of one of the chemical elements, such as hydrogen in the water in the patient's body. The RF pulses force the spin of protons of chemical elements, such as hydrogen, from their magnetically aligned positions and cause the electrons to precess. This precession is sensed to produce electro-magnetic signals that are used to create images of the
30 patient's body. In order to create an image of a plane of patient cross-section, pulsed magnetic fields are superimposed on the high strength static magnetic field.

While researching heart problems, it was found that all the currently used metal stents distorted the magnetic resonance images of blood vessels. As a result, it was impossible to

study the blood flow in the stents and the area directly around the stents for determining tissue response to different stents in the heart region.

A solution, which would allow the development of a heart valve which could be inserted with the patients only slightly sedated, locally anesthetized, and released from the hospital quickly (within a day) after a procedure and would allow the in situ magnetic resonance imaging of stents, has long been sought but yet equally as long eluded those skilled in the art.

The patent literature includes disclosures of a number of stent valves.

US-A-5,957,949 Leonhardt et al discloses a porcine valve in a nickel-titanium shape memory alloy stent delivered to the heart by a catheter system

WO-A-97/13471 Transvascular, Inc. proposes valving transvascular passageways, and Fig. 11A shows a stent with a one-way valve formed by a cylindrical membrane which closes at one end to a planar face-to-face arrangement.

DE-A-196 05 042 Figulla discloses in Fig. 2A as replacement for a heart valve a combination of two semi-cylindrical tubular members arranged flat face to flat face in a bodily lumen. Within each semi-circular cross-section is a valve member.

US-A-5,824,064 Taheri is another disclosure of a stent valve for the aorta, comprising a nickel-titanium stent and a biological valve device within it.

US-A-5,855,597 Jayaraman discloses a replacement aortic valve within a stent. A tri-cuspid valve is proposed, but Fig. 23 illustrates a device with a single valve member spanning the lumen of the stent in which it is mounted. It is said that the conduit which carries the valve member can be of biological or synthetic polymeric material, and that the valve member is in the nature of a patch on this conduit.

EP-A-1 057 460 Numed, Inc. is another disclosure of a stent of wire carrying a valve of material of biological, such as bovine, material.

DISCLOSURE OF THE INVENTION

According to one aspect of the invention, there is provided a valve device in accordance with claim 1 below. The device comprises a valve leaflet supported around a substantial part of its periphery by a wire which moves with the leaflet.

The present invention also provides a heart valve stent and method for treating a patient with a fluid circulatory system defect with the heart valve stent. The heart valve stent has a stent body, which is expandable from a compressed state to an expanded state. The stent

body in the expanded state has a hollow structure and a leaflet attached thereto with the leaflet movable from an open to a closed position respectively to allow unidirectional fluid circulation and to prevent non-unidirectional fluid circulation and acting as a valve for fluid through its hollow structure, which is translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto.

The present invention further provides a stent and method for treating a patient with a fluid circulatory system defect. The stent has a metal stent body, which is expandable from a compressed state to an expanded state. The stent body in the expanded state has a hollow structure, which is translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto.

Valve devices in accordance with the present invention would normally combine the technology of biocompatible synthetic membranes with that of catheter-delivered stents for bodily lumens. Such stents can be balloon expandable. Such stents are usually made of stainless steel and suffer plastic deformation during expansion. The stent invented by Palmaz is exemplary. Other stents are self-expanding by resilient elastic deformation. Exemplary is the Gianturco Z-stent. A third category of stent is that of self-expanding shape memory alloy stents. The nickel-titanium alloy NITINOL is biocompatible, fatigue-resistant, and can be made highly resilient at body temperature.

Self-expanding stents are attractive for the present invention, because then the valve device does not displace any inflation balloon. The stent is prevented from premature radial expansion by a sheath radially outside the stent.

Shape memory alloy stents can be made of wire or sheet. The sheet can be flat or tubular. As the leaflet in preferred embodiments of the present invention is supported on its periphery by wire, it may be attractive to build the stent and the membrane support both from the same wire material. Alternatively, a wire support can be readily combined with a sheet material stent.

The membrane can be from any suitable material, but the presently preferred material is polytetrafluoroethylene. While at present a single leaflet is favored, it is also contemplated to provide devices in which two, three or even more leaflets combine to occlude the lumen of the stent.

The above and additional advantages of the present invention will become apparent to those skilled in the art from a reading of the following detailed description of preferred embodiments, when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a top view of a single leaflet;
- FIG. 2 is a side view of the single leaflet;
- 5 FIG. 3 is a top view of a stent body;
- FIG. 4 is a side view of the stent body of Fig. 3;
- FIG. 5 is a top view of a heart valve stent, in an open position;
- FIG. 6 is a side view of the heart valve stent of Fig. 5 in an open position;
- FIG. 7 is a side view of a step in manufacturing one embodiment of the heart valve
- 10 stent;
- FIG. 8 is a top view of the heart valve stent of Fig. 5 in a closed position;
- FIG. 9 is a side view of the heart valve stent of Fig. 5 in a closed position;
- FIG. 10 is an isometric view of spring-type embodiment of a valved stent of the present invention;
- 15 FIG. 11 is an isometric view of a closed-loop spring-type embodiment of a valved stent of the present invention;
- FIG. 12 is an isometric view of another embodiment of stent, having a material connected to spaced-apart-rings;
- FIG. 13 is a top view of the embodiment of Fig. 12;
- 20 FIG. 14 is a drawing illustrating the placement of a heart valve stent body of the present invention at the aorta in a human heart; and
- FIG. 15 is a drawing illustrating the placement of a heart valve stent at the pulmonary truncus in a human heart.

BEST MODE FOR CARRYING OUT THE INVENTION

- 25 Referring now to FIG. 1, therein is shown a top view of a leaflet 10, a component of a heart valve stent made in accordance with the present invention. The leaflet 10, which in top

view is circular, is made of polytetrafluoroethylene material, trademarked TEFLON, manufactured by several companies such as W.L. Gore & Co., Elkton, Maryland, USA.

Referring now to FIG. 2, therein is shown a side view of the leaflet 10. The leaflet 10 comprises a contact-lens-shaped membrane with a diameter of 18 millimeter (mm) and a
5 constant thickness in a range from of 0.1 mm to 0.3 mm. In other embodiments, the membrane is flat.

With the above-specified dimensions, the leaflet 10 is capable of resisting up to 140 mm pressure of mercury over many years when supported around its perimeter without falling through the support. The leaflet 10 may also be made from the fibroserous sac
10 surrounding the heart and the roots of the blood vessels, i.e., the pericardial membrane. The leaflet 10 may also be made from abdominal tissue, namely the serosa, and may also be made from venous or arterial native valve tissue.

Ideally, the leaflet 10 should be substantially free from any tissue in-growth. To limit the tissue in-growth, a layer of endothelial cells may be plated on the leaflet 10. These
15 endothelial cells stop other cells from growing over the surface of the leaflet 10. As an equivalent, radioactive or anti-cancer products that prevent other tissue cells from growing may also be applied to the surface of the leaflet 10.

Referring now to FIG. 3, therein is shown a top view of a stent body 14 of a heart valve stent in accordance with the present invention, which stent body can be produced by the
20 Applicant at Karlsruhe, Germany. The stent body 14 is made from Nitinol, a nickel-titanium shape memory metal alloy, and has a hollow structure with a luminal wall surface 15. The United States Federal Drug and Food Administration (FDA) has approved Nitinol for use in human medical applications.

Referring now to FIG. 4, therein is shown a side view of the stent body 14 in an
25 expanded configuration showing a proximal end 16 and a distal end 18 and a tubular wall 20 disposed between the proximal end 16 and the distal end 18. The tubular wall 20 has a longitudinal axis and a mesh cylinder 22 defined by a plurality of intersecting members arranged to define a repeating pattern of polygons having a pair of inside and outside
sidewalls substantially parallel to the longitudinal axis. The stent body 14 is hollow and has a
30 diameter of 18 millimeters or larger. The diameter of the leaflet 10 of FIG. 1 is smaller than that of the stent body 14, in the radially expanded configuration of Fig. 4.

As also shown in FIG. 4, a Teflon sleeve 24 is attached around the proximal end 16 of the mesh cylinder 22, generally by a heating technique. The Teflon sleeve 24, which has a

thickness of less than 0.1 mm with a width of 2 mm to 4 mm, covers the strut structure of the stent body 14 to prevent tissue growth into the stent body 14. The Teflon sleeve 24 may cover the abluminal outside surface or the luminal inside surface of the mesh cylinder 22. It may also cover the proximal end 16 edge of the mesh cylinder 22.

5 Referring now to FIG. 5, therein is shown a top view of a heart valve stent 25 of the present invention with the leaflet 10 in an open position which would permit a unidirectional fluid flow through the hollow structure of the stent body 14. A leaflet-attaching wire 30 of the stent body 14 is also shown with the leaflet 10 in an open position. The leaflet-attaching wire 30 has a diameter in a range of from 0.1 mm to 0.2 mm and encircles the outer periphery of
10 the leaflet 10.

In the illustrated embodiment of the present invention, the leaflet-attaching wire 30 is attached to the stent body 14 by welding it onto the stent body 14 at two welding points 32 and 34. The leaflet-attaching wire 30 is further flexibly attached to the mesh cylinder 22 at a plurality of attaching points by running through the open structure of the mesh cylinder 22 in
15 a circle. The two welding points are also two of the attaching points. The leaflet-attaching wire 30 runs from the welding point 32 and continues around the long direction to form a sling, or loop, for the leaflet 10 before continuing to the other welding point 34. The leaflet 10 is attached to the wire 30 by a heating technique.

This way of attaching the leaflet-attaching wire 30 to the mesh cylinder 22 has a great
20 advantage. The attachment forces are distributed over the entire surface of the stent body 14 at a plurality of attaching points. Therefore, the heart valve stent 25 displays more mechanical strength to resist wear-and-tear due to a tremendous number of openings and closings in the blood vessels over many years during a patient's life time. Thus the reliability and durability of the heart valve stent 25 is enhanced.

25 In detail, the leaflet-attaching wire 30 originates from the welding point 32 on the front side of the stent body 14 and continues to the back part of the stent body 14. It goes around almost half way to the back of the stent body 14 and then leaves; it follows the axis of the tube up and around, forming a cross-point. After leaving the circumference to form the sling, or the loop, to which the leaflet 10 is attached, the leaflet-attaching wire 30 comes back
30 to the circumference and crosses over again to form the second cross-point. Continuing along the circumference, it finally ends at the welding point 34 on the front side of the stent body 14. A hinge 38 is formed by the two cross-points at the back of the stent body 14. The hinge 38 may be very long or very short, depending on the distance between the cross-points. The

location of the hinge 38 is determined by where the leaflet-attaching wire 30 departs from the circumference.

As shown in FIG. 5, the welding points 32 and 34 are not fixed at certain location on the leaflet-attaching wire 30; instead, they may move around the attaching wire on the stent body 14 and cross over to stay stable. The welding points 32 or 34 may stay close to each other or far apart from each other or they may run in parallel.

This brings both advantages and disadvantages. The advantage of the welding points 32 and 34 being close to each other is that, even if tissue grows into the stent body 14, the presence of tissue will not significantly inhibit the function of the heart valve. However, the hinge 38 will suffer more mechanical stress across a short length and be subject to greater risk of failure. If the welding points are widely apart, the advantage is that the mechanical stress is distributed over a longer length. However, the disadvantage lies in that some tissue overgrowth is likely to occur on the longer length and thus inhibit the function of the heart valve stent 25.

In addition to the leaflet-attaching wire 30, FIG. 5 further shows a top view of one other component of the heart valve stent body 14, namely a leaflet-retaining wire 40. The leaflet-retaining wire 40, which is also made of the memory alloy Nitinol, in this embodiment is a thin wire with a thickness of 0.1 millimeter. Of course, other leaflet-retaining devices are conceivable, as well as other wire materials and diameters. The leaflet-retaining wire 40 is flexibly secured to the stent body 14 and crossed at a crossing point 42. Its purpose is to prevent the leaflet 10 falling backward inside of the stent body 14 beyond a closed position. The leaflet retaining wire 40 supports the leaflet 10 in the closed position, against such backward movement, during the diastole phase of the cardiac cycle, which is the dilatation period when atrial and ventricular muscle fibers are elongated and the four chambers of the heart are rapidly filled with blood.

The leaflet retaining wire 40 is shaped as follows. The leaflet-retaining wire 40 is anchored at points 44 and 46, as shown in FIG. 5, and is flexibly secured to the stent body 14 at a plurality of anchoring points and extends across the hollow of the stent body 14 and is crossed at the crossing point 42 away from the hinge 38. The two anchoring points 44 and 46 may move with the attaching points of the leaflet-attaching wire 30 around the structures of the stent body 14.

Furthermore, the construction of the leaflet-retaining wire 40 is designed to allow repair or replacement of an old heart valve stent by replacement with a new heart valve stent

if the old one becomes dysfunctional after several years. The leaflet-retaining wire 40 could otherwise block the way; therefore the leaflet-retaining wire 40 is designed to be long enough to move out of the way and avoid this problem.

Upon the application of longitudinally upward force against the leaflet-retaining wire 40, the crossing point 42 moves across the hollow structure to a crossing point 48 and can be twisted out of the way. A new heart valve stent or other new endovascular device components, such as catheters, may be placed coaxially and concentrically within the old heart valve stent.

The leaflet-retaining wire 40 has approximately the same length as the distance between point 44 and point 46 along the outer circumference because the leaflet 10 is attached to the stent body 14 at its base where the leaflet 10 is held in place. The length is also necessary for the stability of the attached leaflet 10. Furthermore, on the opposite side of the hinge 38 where the leaflet 10 is attached to the stent body 14, the leaflet-retaining wire 40 provides support at the epical part of the leaflet 10. The crossing point 42 should be approximately two-thirds of the diameter of the stent body 14 away from hinge 38.

Like the leaflet-attaching wire 30, the remainder of the leaflet-retaining wire 40 runs through the mesh cylinder 22 of the stent body 14. The advantages of the arrangement are that both the attaching and retaining wires may be easily attached by welding, without a need to turn the stent body 14. In addition, the leaflet 10, the leaflet-retaining wire 40, and the leaflet-attaching wire 30 may be compressed and forced outside the stent body 14 so that the stent may be brought into a small diameter delivery system, such as one of diameter around eight to ten French (one French is one third of a millimeter).

Referring now to FIG. 6, therein is shown a side view of a heart valve stent 25 with the leaflet 10 at an open position. The leaflet-attaching wire 30 and leaflet-retaining wire 40 of the stent body 14 are also shown with the leaflet 10 at an open position. Both the leaflet-retaining wire 40 and the leaflet-attaching wire 30 have a thickness in a range of from 0.1 mm to 0.2 mm. The wires can be fabricated and attached to the stent body 14 in a number of ways. For example, they can be welded onto the stent body 14 or laser cut out of a tube, together with the stent body 14, in the same process.

Referring now to FIG. 7, therein is shown a step in manufacturing the stent body 14 and the leaflet-attaching wire 30 by a laser technique. A laser beam 50 from a laser 52 cuts the stent body 14 and the leaflet-attaching wire 30 out of a tube 54 made of Nitinol and having a first thickness on one end and a second thickness on the other end which is more

than the first thickness. This result is achieved by a process of lasering out the mesh of the mesh cylinder 22 and the leaflet-attaching wire 30 out of the tube 54 and decreasing or increasing the stability of the leaflet-attaching wire 30. A lasered edge 56 is shown in FIG. 7. The tube 54 is fabricated in a fashion such that the part of the tube 54 out of which the stent
5 body 14 is cut out by a laser is thicker than the part of the tube where the leaflet-attaching wire 30 is being cut out. The tube 54 is thicker on the one side and thinner on the other side of the tube. The wall thickness can be decreased due to the leaflet-attaching wire 30 by 1 mm. Consequently, the wall of the stent body 14 is thicker at one side and thinner at the other side.

Referring now to FIG. 8, therein is shown a top view of a heart valve stent 25 of the
10 present invention with the leaflet 10 in a closed position. The leaflet 10 is held in place at point 38, the location where the leaflet 10 is attached to the stent body 14 at its base. The crossing point 42 is on the opposite side of the hinge 38.

Referring now to FIG. 9, therein is shown a side view of a heart valve stent 25 of the
15 present invention in a closed position which would prevent flow longitudinally downward through the hollow structure.

The heart valve stent 25 described herein is a unidirectional fluid flow, mechanical mono-valve, i.e., a valve with one leaflet. Ordinary biological valves of the left and right-sided outflow tracts of the heart have three leaflets. As would be evident to those skilled in the art, bicuspid (dual) and tricuspid (triple) valves may also be constructed in accordance with
20 the present invention with respective dual and triple leaflets.

The conventional mechanical valves often cause damage to the corpuscles, i.e., the blood cells. There are two reasons. First, the mechanical valves are placed by surgery in place of the biological valves. The surgical invasion inevitably introduces turbulence and abnormal blood flow patterns. Secondly, the nature of the mechanical properties of the mechanical
25 valves exacerbates the problem. For example, the articulation structures (such as the hinges) and the sealing regions often pinch the blood cells. The debris and residuals of the dead blood cells serve as nuclei for blood clots and thus accelerate the process of blood coagulation, paving the way for tissue overgrowth on the valve and the structural dysfunction that may lead to the death of the patient. The conventional mechanical valves that are commercially
30 available all suffer from this problem.

The mechanical design in the present invention, coupled with the choice of materials, solves the problems. Both the nickel-titanium alloy and polytetrafluoroethylene are compatible with biological systems. Teflon has been proven to be a suitable material in many

other aspects of cardiovascular surgery, for example, repairs by surgery in congenital heart diseases are usually conducted by utilizing a tube made of Teflon to bring shunts from one artery or vein to another artery or vein. Cardiovascular surgeons are familiar with manipulation of surgical instruments made of Teflon. The hemodynamics of the heart valve
5 stent disclosed herein has been shown to be close to a physiological condition. The present invention should permit magnetic resonance imaging (MRI) sufficient to reveal that the blood flow patterns closely resemble what is normal in the blood vessels without having a stent. It should be noted that the present invention permits the blood flow patterns through the heart valve stent 25 to be determined, as will later be explained.

10 Another major advantage of the present invention is that the leaflet 10 may also be replaced by a structure that is made of a matrix of biological molecules including collagen and endothelial cells formed by a bio-engineering process. The matrix consists of an array of proteins called collagen. A layer of endothelial cells, which are components of the inside layer of blood vessels, is plated to grow on the matrix of biological molecules including
15 collagen. The endothelial cells further expand onto the leaflet-attaching wire 30 of the stent body 14. The bio-engineered matrix has enormous advantages because the endothelial cells plated on the leaflet 10 will regenerate and repair themselves when damage occurs. Furthermore, if there is any leakage or any change in the hemodynamics within the blood vessels, the endothelial cells will re-adapt themselves to the new physiological condition.

20 Another improvement of the present invention is directed to the material used for the stent body 14. The stent body 14 disclosed herein may also be made of biodegradable materials. Young children show fair amount of growth in their arteries. Accordingly, the heart valve stents 25 need to be replaced periodically by stents of larger diameter, to be in accordance with the inner diameters of the blood vessels. Bio-degradable heart valve stents
25 would allow surgeons to treat children who cannot be treated using currently available technology because the dimensions of the conventional stents are not capable of adapting themselves to the dimensions of growing blood vessels.

One group of bio-degradable materials, for example, is iron or oxidized iron. A second group of materials are polyesters, which can be dissolved in the body. Experiments
30 with stent bodies made of these materials have been performed on animals. However, they have caused significant inflammatory reactions to the surrounding tissues several weeks after they are placed. Therefore, they are not yet suitable for humans.

Another advantage of the present invention is the manner in which the leaflet 10 is attached onto the stent body 14 by the leaflet-attaching wire 30. Conventional mechanical valves have articulations at the bases that allow the valves to open and close. The articulation points are always the places of complications because of tissue in-growth. Tissue in-growth
5 brings such high stiffness to the articulation points that the valve would stay in one position, failing to open or close anymore after a while. In present invention, in contrast, the leaflet valve is attached to the stent in a floppy way, that is to say, a way free of fixed hinge points. The leaflet-attaching wire 30 is flexibly attached to the valve at a plurality of attaching points and the leaflet-retaining wire 40 is also flexibly secured to the mesh cylinder at a plurality of
10 anchoring points. By employing these floppy components, the problem of the tissue overgrowing at the fixed points of the attaching wire is alleviated or even eliminated.

Referring now to FIG. 10, therein is shown an isometric view of spring-type embodiment 60 of the present invention, which has a stent body 62 of a single open-ended wire. The stent body 62 has a hollow structure which renders the stent body 62 translucent to
15 MRI signals; by translucent it is meant that the stent body 60 may be seen on an MRI image but fluid flow can also be seen in the hollow structure of the stent body. For simplicity, a leaflet is not shown which would make the stent body 60 into a heart valve stent, but the stent body 60 can be covered by a Teflon sleeve and the stent body 60 can be bent to form a leaflet-retaining wire.

As previously explained, MRI is used to non-invasively produce medical information.
20 The patient is positioned in an aperture of a large annular magnet, which produces a strong and static magnetic field, which forces hydrogen in the patient's body into alignment with the static field. A series of radio frequency (RF) pulses are applied orthogonally to the static magnetic field at the resonant frequency of spins of protons of chemical elements such as
25 hydrogen. The precession caused by the RF pulses is sensed to produce electro-magnetic signals that are used to create images of the patient's body.

While researching heart problems, it was found that all the currently used metal stents distorted the magnetic resonance images. As a result, it was impossible to study the blood flow in the stents which were placed inside blood vessels and the area directly around the
30 stents for determining tissue response to different stents in the heart region.

It was found that metal of the stents distorted the magnetic resonance images of blood vessels. The quality of the medical diagnosis depends on the quality of the MRI images. A proper shift of the spins of protons in different tissues produces high quality of MRI images.

The spin of the protons is influenced by radio frequency (RF) pulses, which are blocked by eddy currents circulating at the surface of the wall of the stent. The RF pulses are not capable of penetrating the conventional metal stents. Similarly, if the eddy currents reduce the amplitudes of the radio frequency pulses, the RF pulses will lose their ability to influence the spins of the protons. The signal-to-noise ratio becomes too low to produce any quality images inside the stent. The high level of noise to signal is proportional to the eddy current magnitude, which depends on the amount and conductivity of the stent in which the eddy currents are induced and the magnitude of the pulsed field.

One important advantage of the present invention is that it allows non-invasive means to determine the conditions within or surrounding a stent or a heart valve stent. The invention allows doctors to monitor or determine the conditions of the heart valve or any desired area without bringing instrumentation into the human body. It becomes possible to find out whether there is the back-flowing blood through the leaflet, i.e., regurgitation, and whether there is occurring any mechanical or other character changes of the leaflet. Similarly, non-invasive diagnosis of restenosis caused by heavy tissue in-growth and obstruction of the blood flow through the hollow structure of the stent body or obstruction the blood flow caused by thick tissue growth on a leaflet pose significant challenges to doctors without resorting to the MRI technology.

An advantage of MRI treatment lies in its non-invasive nature. Cross-sections of the images within a patient body can be produced on a computer screen in short time without subjecting the patients to the traumatic experiences of a surgery, especially an open heart surgery. By using this technology, many medical inquiries can be accomplished without bringing any foreign instrument into the body of a patient by a doctor. For example, an accurate quantification of the blood flow in the pulmonary artery or in the aorta may be made within only thirty minutes by MRI technology. A MRI image will show whether a stent body is still open allowing blood to flow through or whether a leaflet opens and closes properly. Whether an obstruction of the blood vessels occurs or not can also be detected on a MRI image.

It has been unexpectedly discovered that slight changes and improvement of the design and structure of a metallic stent body will result in enormous amount of penetration by RF pulses so that the signal-to-noise ratio increases and the images inside the stent improve significantly. The MRI-ideal open design is the open spring configuration 60, shown in FIG.

10. No eddy currents can be established within this coil because the open coil configuration 60 is an open circuit where no current can flow through within it.

Referring now to FIG. 11, therein is shown an isometric view of a closed-loop spring-type embodiment 64 of the present invention, which has a stent body 66 of a single wire
5 connected end-to-end with an electrical diode 68. The electrical diode 68 allows only a unidirectional current flow in the wire. Therefore, the closed-loop spring-type embodiment 64 provides a circuit that does not allow eddy currents to be created and a high quality MRI image is possible that allows accurate medical diagnosis.

Referring now to FIG. 12, therein is shown an isometric view of a "material connected
10 to spaced-apart-rings" embodiment 70 of the present invention which has a plurality of thin rings 72 held together by a material 74 such as Teflon. The metal of the thin rings 72, if the rings are closed ended, will create eddy currents within the rings themselves but the large spacing between the Nitinol rings allows the penetration of the radio frequency pulses which result in improved image quality.

Referring now to FIG. 13, therein is shown a top view of material connected to
15 spaced-apart-rings. While previous descriptions of the compressed heart valve stent 25 were described as being made of Nitinol alloy, the embodiment 70 of stent with the material connected to spaced-apart-rings 72 has a longitudinal catch 76 and the thin rings 72 are open-ended. The stent can be compressed into a spiral compressed state 66 and inserted into a
20 long sheath 78. Because the thin rings 72 are open-ended, they will not create eddy currents in the expanded state.

Referring now to FIG. 14, therein is shown a drawing illustrating the placement of the heart valve stent 25 at the aorta in a human heart 80. The surgery is accomplished taking the heart valve stent 25 in a compressed state and inserting into an artery, e.g., a groin artery,
25 under local anesthesia. The heart valve stent 25 could be a self-expanding stent in a compressed state in a sheath or a balloon-expandable stent, awaiting plastic deformation induced by the inflation of a balloon inside. With the help of MRI images, the heart valve stent 25 with the leaflet 10 can be placed in the desired position. Once in place, the sheath would be removed, or the balloon inflated, to provide outward force to cause the heart valve
30 stent 25 to expand to its expanded state having a hollow structure translucent to MRI signals. The subsequent MRI images are used to assure that the heart valve stent 25 is properly positioned and operating properly.

Self-expanding stent bodies are preferred, because the absence of an inflation balloon allows more room for the valve leaflet during delivery and prior to radial expansion of the stent body.

Referring now to FIG. 15, therein is shown a drawing illustrating the placement of the heart valve stent 25 at the pulmonary truncus in a human heart 80. The surgery is accomplished with the heart valve stent 25 in a compressed state and inserting it into a vein under local anesthesia.

In another aspect the invention provides a method of treating a patient with a fluid circulatory system defect, comprising: providing a stent expandable from a compressed state to an expanded state; inserting the stent surgically under local anesthesia at a first point in the circulatory system in a contracted state; guiding the stent to a second point in the fluid circulatory system; and expanding the stent to the expanded state to correct the fluid circulatory system defect, the stent in the expanded state having a hollow structure translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto. The method can include: imaging the fluid circulatory system by magnetic resonance imaging signals to view fluid circulation inside of the hollow structure translucent to magnetic resonance signals. The method can be one in which: the stent provides a stent having a leaflet attached thereto, the leaflet movable to allow unidirectional fluid circulation through the hollow structure translucent to magnetic resonance imaging signals. The method can be one in which: the stent provides a leaflet of a material from a group consisting of: a biological tissue, a biologically compatible synthetic material, and a matrix of biological molecules. The method can be one in which: the stent provides a stent body made from a memory metal having the a single leaflet attached thereto, the single leaflet of a material containing a memory metal movable to allow unidirectional fluid circulation through the hollow structure translucent to magnetic resonance imaging signals. The method can be one in which: the stent provides a stent body having a hollow structure translucent to magnetic resonance imaging signals selected from bodies consisting of a spring-type stent body, a closed-loop spring-type stent body with a unidirectional current device in the closed-loop, a material connected to spaced-apart-rings stent body, and a combination thereof. The method can be one in which: expanding the stent includes expansion by a process selected from a group consisting of: enclosing the stent in the compressed state in a sheath and removing the sheath; and compressing the stent and forcing the stent to expand by application of force inside the hollow structure thereof. The method can include the step of: inserting a new

device to be coaxial with the stent. In another aspect, the present invention provides a method of treating a patient with a fluid circulatory system defect, comprising: a stent expandable from a compressed state to an expanded state; inserting the stent surgically under local anesthesia at a first point in the circulatory system in a contracted state; guiding the stent to a
5 second point in the fluid circulatory system; and expanding the stent to the expanded state to correct the fluid circulatory system defect, the stent in the expanded state having a hollow structure and a leaflet attached thereto, the leaflet movable to allow unidirectional fluid circulation through the hollow structure. This method can be one in which: the stent provides the leaflet of a material from a group consisting of a biological tissue including pericard
10 serosa, and native valve tissue, a biologically compatible synthetic material including Teflon, and a matrix of biological molecules including collagen and covering endothelial cells on the leaflet. The method can be one in which: the stent provides a stent body made from a memory metal having the leaflet as a single leaflet attached thereto, the single leaflet of a memory metal extendable out of the stent body to allow the unidirectional fluid circulation and
15 positionable in the stent body to block the non-unidirectional fluid circulation. The method can include the step of: expanding the stent to the expanded state expands the hollow structure and the leaflet of the stent to be translucent to magnetic resonance imaging signals. The method can include: imaging the fluid circulatory system by magnetic resonance imaging signals to view fluid circulation inside of the hollow structure translucent to magnetic
20 resonance imaging signals and movement of the leaflet by not producing eddy currents in response thereto. The method can be one in which: the stent provides a stent body having the leaflet and the hollow structure translucent to magnetic resonance imaging signals, the hollow structure selected from bodies consisting of a spring-type stent body, a closed-loop spring-type stent body with a unidirectional current device in the closed-loop, a material connected
25 to spaced-apart-rings stent body, and a combination thereof. The method can be one in which: the stent includes expansion by a process selected from a group consisting of: enclosing the stent in the compressed state in a sheath and removing the sheath; and compressing the stent and forcing the stent to expand by application of force inside the hollow structure thereof. The method can be one in which: the stent provides a stent having a hollow structure formed
30 from a memory metal having a proximal end and a distal end and a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members formed to define a repeating pattern comprised of a polygon having a pair of sidewalls substantially parallel to the

longitudinal axis; providing the stent provides a stent having a leaflet frame wire flexibly integral with the hollow structure at a plurality of anchoring points and crossed at a crossing point to provide a hinge, the leaflet frame wire supporting a material to prevent fluid flow therethrough; and providing the stent provides a stent having a leaflet retaining wire flexibly
5 integral with the hollow structure at a plurality of anchoring points and crossed at a crossing point to stop the leaflet from moving to a non-unidirectional flow position, the stent leaflet retaining wire movable to permit coaxial disposition of a further stent inside the stent. The method can include the step of: inserting a new stent to be coaxial and concentric with the stent.

10 While the invention has been described in conjunction with a specific best mode, it is to be understood that many alternatives, modifications, and variations will be apparent to those skilled in the art in light of the foregoing description. Accordingly, it is intended to embrace all such alternatives, modifications, and variations which fall within the spirit and scope of the included claims. All matters hither-to-fore set forth herein or shown in the
15 accompanying drawings are to be interpreted in an illustrative and non-limiting sense.

CLAIMS:

1. A valve device comprising an elongate, self-expanding, medical stent for a bodily lumen, which stent has a radially-compressed delivery configuration and a radially-expanded deployed configuration, the stent defining in said deployed configuration a
5 stent lumen for flow of a bodily fluid lengthwise with respect to the stent within the bodily lumen and lengthwise within the bodily lumen, the stent supporting a valve leaflet which can move, in the deployed configuration to of the stent, between an open configuration to allow fluid flow along said stent lumen in one direction and a closed
10 configuration in which the leaflet resists fluid flow along the stent lumen in a direction opposite to said one direction;
characterised in that:
said leaflet has a free periphery unattached to the stent and a resilient wire which extends around a substantial part of the length of said free periphery whereby, upon
15 self-expansion of the stent from the delivery to the deployed configuration, the wire brings the leaflet into a disposition in which the leaflet extends across the stent lumen to an extent sufficient to permit fluid pressure differentials across the ends of the stent lumen to move the leaflet between its open and closed configurations.
- 20 2. A valve device as claimed in claim 1 wherein the stent is made of a nickel-titanium shape memory alloy.
3. A valve device as claimed in claim 1 or 2 wherein the stent is formed from tube stock.
- 25 4. A valve device as claimed in any one of the preceding claims wherein the resilient wire is of the same material as the stent.
5. A valve device as claimed in any one of the preceding claims, wherein the leaflet is made of polytetrafluoroethylene.
- 30 6. A valve device as claimed in any one of the preceding claims, having only one leaflet.
7. A valve device as claimed in any one of the preceding claims wherein said resilient wire extends in a loop having a cross-sectional area corresponding to that of the stent
35 in its deployed configuration, the wire in a hinge zone to establish a hinge about which the leaflet pivots between its open and closed configuration, the loop ends beyond the hinge zone being attached to the stent so that any pivoting of the leaflet

changes a pattern of shear stress suffered by the wire within those portions of its length which lie within the hinge zone.

- 5 8. A valve device as claimed in claim 7, in which the wire is attached to the stent with the wire loop spanning the stent lumen, so that shear stresses within the wire in the hinge zone are at a minimum when the leaflet spans the stent lumen, thereby providing a restoring force to bring the leaflet back to a configuration spanning the stent lumen wherever the leaflet is displaced from such a configuration.
- 10 9. A valve device as claimed in any one of the preceding claims, within a delivering system which comprises an outer sheath and an inner shaft, expansion of the stent to the deployed configuration being denied by the sheath, such expansion being actuated by a proximal withdrawal of the sheath while using the shaft to prevent the stent from moving proximally with the sheath.
- 15 10. A valve device as claimed in claim 9 arranged to be advanced over a guide wire while in the delivery configuration, the guide wire extending lengthwise through the stent lumen.
- 20 11. A stent for treating a patient with a fluid circulatory system defect, comprising:
a stent body expandable from a compressed state to an expanded state; and
the stent body in the expanded state having a hollow structure and a leaflet attached thereto, the leaflet movable from an open to a closed position to allow unidirectional fluid circulation and to prevent non-unidirectional fluid circulation through the hollow
25 structure.
12. The stent as claimed in claim 11 including:
the leaflet of a material from a group consisting of:
a biological tissue,
30 a biologically compatible synthetic material, and
a matrix of biological molecules.
13. The stent as claimed in claim 11 wherein:
the leaflet is attached to one end of the stent body by a memory metal wire secured in
35 a plurality of locations to the stent body to form a hinge; and

the stent body includes a memory metal retaining wire secured in a plurality of locations to the stent body to cross in the hollow structure and to stop the leaflet to block the non-unidirectional fluid circulation.

- 5 14. The stent as claimed in claim 11 wherein the stent body is made from a memory metal having the leaflet as a single leaflet attached thereto, the single leaflet having a material over a memory metal rim and extendable out of the stent to allow the unidirectional fluid circulation and stoppable by the stent to block the non-unidirectional fluid circulation.
- 10 15. The stent as claimed in claim 11 wherein the stent body in the expanded state has the hollow structure and the leaflet translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto.
- 15 16. The stent as claimed in claim 11 wherein the stent body has the leaflet and the hollow structure translucent to magnetic resonance imaging signals, the hollow structure selected from bodies consisting of a spring-type stent body, a closed-loop spring-type stent body with a unidirectional current device in the closed-loop, a material connected to spaced-apart-rings stent body, and a combination thereof.
- 20 17. The stent as claimed in claim 11 wherein the stent body is in an initial state selected from a group consisting of: the compressed state in a sheath and expandable to the expanded state upon removal of the sheath; and in the normal compressed state and expandable by application of outward force inside the hollow structure thereof.
- 25 18. The stent as claimed in claim 11 wherein:
the stent body has a hollow structure formed from a memory metal having a proximal end and a distal end and a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of intersecting members formed to define a repeating pattern comprised of a polygon having a pair of sidewalls substantially parallel to the longitudinal axis;
- 30

the stent body has a leaflet frame wire flexibly integral with the hollow structure at a plurality of anchoring points and crossed at a crossing point to provide a hinge, the leaflet frame wire supporting a material to prevent fluid flow therethrough; and

5 the stent body has a leaflet retaining wire flexibly integral with the hollow structure at a plurality of anchoring points and crossed at a crossing point to stop the leaflet from moving to a non-unidirectional flow position, the leaflet retaining wire movable to permit coaxial disposition of a further stent inside the stent body.

10 19. A stent for treating a patient with a fluid circulatory system defect, comprising:
a metal stent body expandable from a compressed state to an expanded state; and
the stent body in the expanded state having a hollow structure translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto.

15 20. The stent as claimed in claim 19 wherein the stent body has a leaflet attached thereto, the leaflet movable to allow unidirectional fluid circulation through the hollow structure translucent to magnetic resonance imaging signals.

20 21. The stent as claimed in claim 20 including:
the leaflet of a material from a group consisting of:
a biological tissue including pericard, serosa, and native valve tissue,
a biologically compatible synthetic material including Teflon, and
a matrix of biological molecules including collagen and covering endothelial cells on the leaflet.

25 22. The stent as claimed in claim 19 wherein the stent body is made from a memory metal having the a single leaflet attached thereto, the single leaflet of a material containing a memory metal movable to allow unidirectional fluid circulation through the hollow structure translucent to magnetic resonance imaging signals.

30 23. The stent as claimed in claim 19 wherein the stent body is a hollow structure translucent to magnetic resonance imaging signals selected from bodies consisting of a spring-type stent body, a closed-loop spring-type stent body with a unidirectional

current device in the closed-loop, a material connected to spaced-apart-rings stent body, and a combination thereof.

24. The stent as claimed in claim 19 wherein the stent body is in an initial state selected from a group consisting of: the compressed state in a sheath and expandable to the expanded state upon removal of the sheath; and in the normal compressed state and expandable by application of outward force inside the hollow structure thereof.
25. A method of treating a patient with a fluid circulatory system defect, comprising:
- a stent expandable from a compressed state to an expanded state;
 - inserting the stent surgically under local anesthesia at a first point in the circulatory system in a contracted state;
 - guiding the stent to a second point in the fluid circulatory system; and
 - expanding the stent to the expanded state to correct the fluid circulatory system defect, the stent in the expanded state having a hollow structure translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto.

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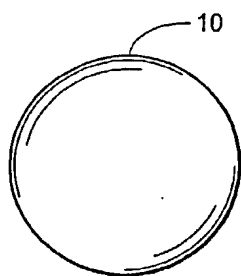


FIG. 1



FIG. 2

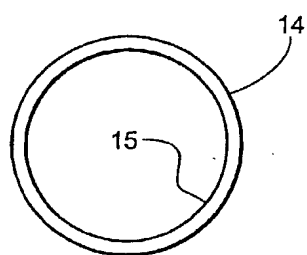


FIG. 3

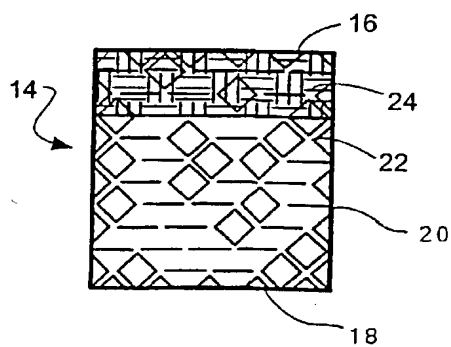
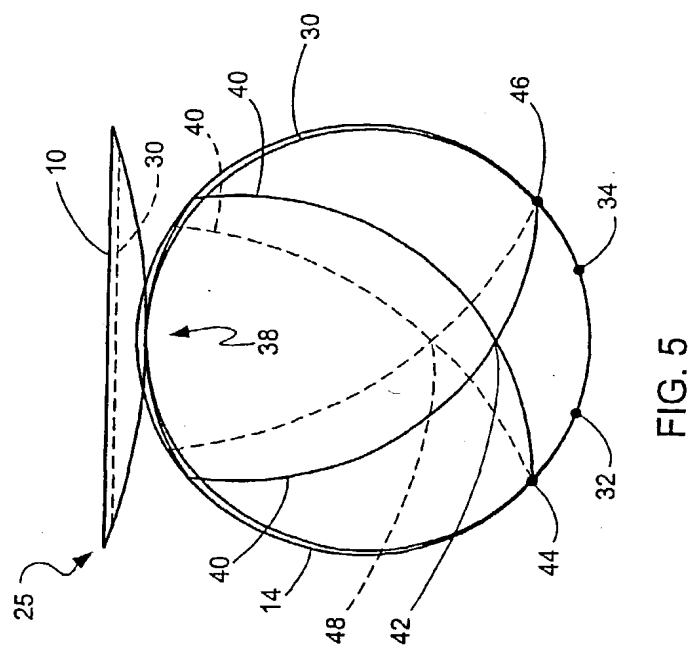
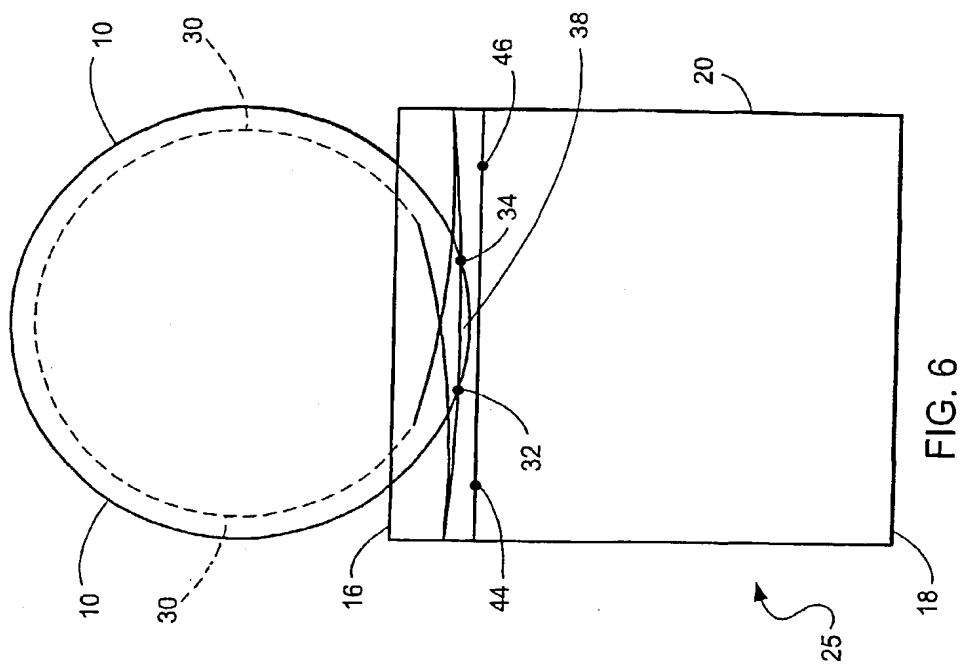


FIG. 4

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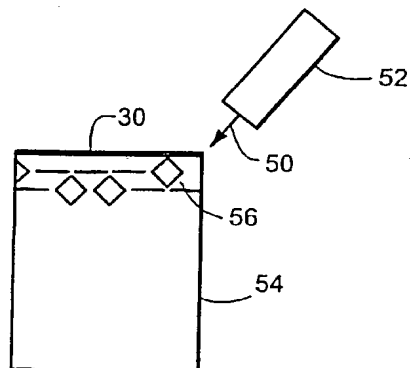


FIG. 7

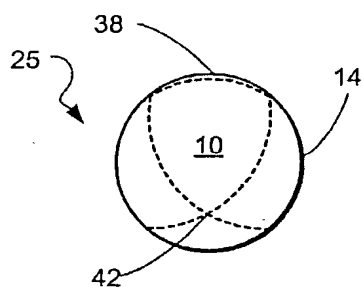


FIG. 8

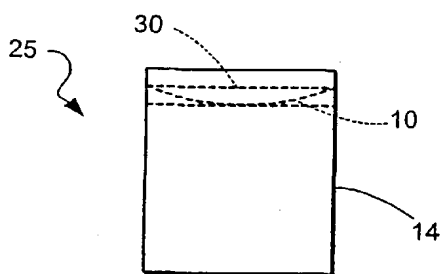


FIG. 9

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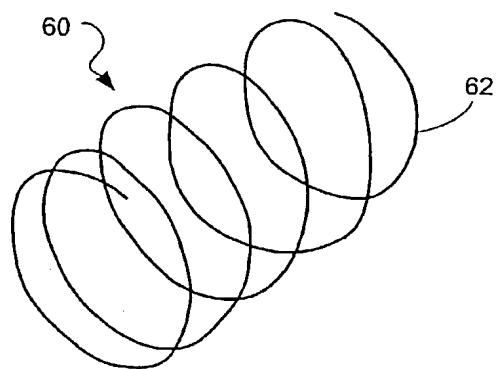


FIG. 10

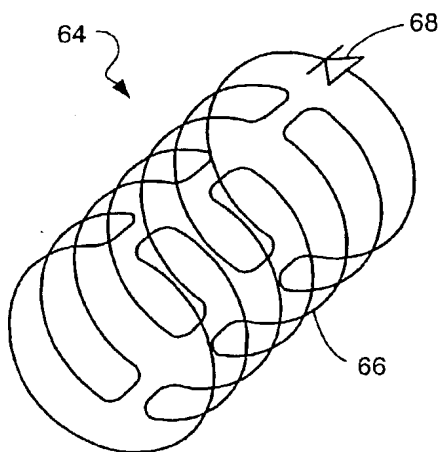


FIG. 11

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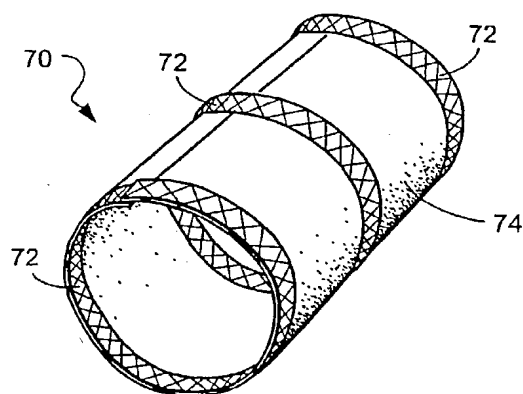


FIG. 12

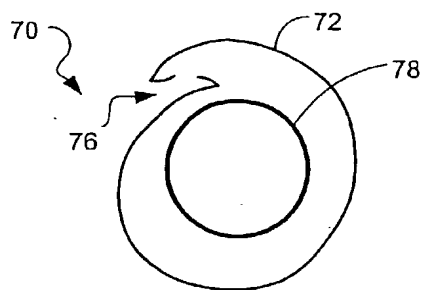


FIG. 13

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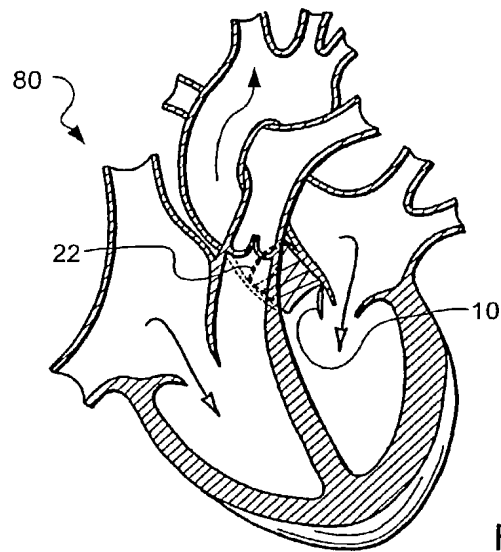


FIG. 14

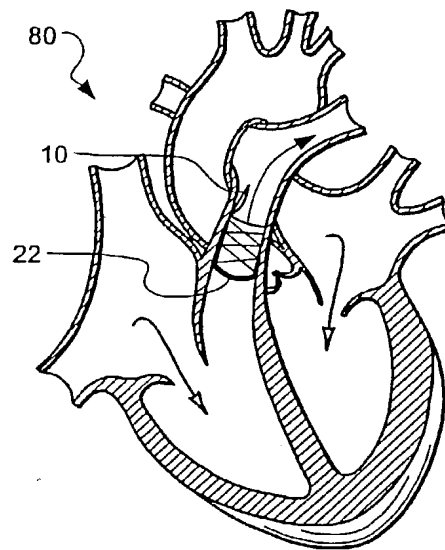


FIG. 15

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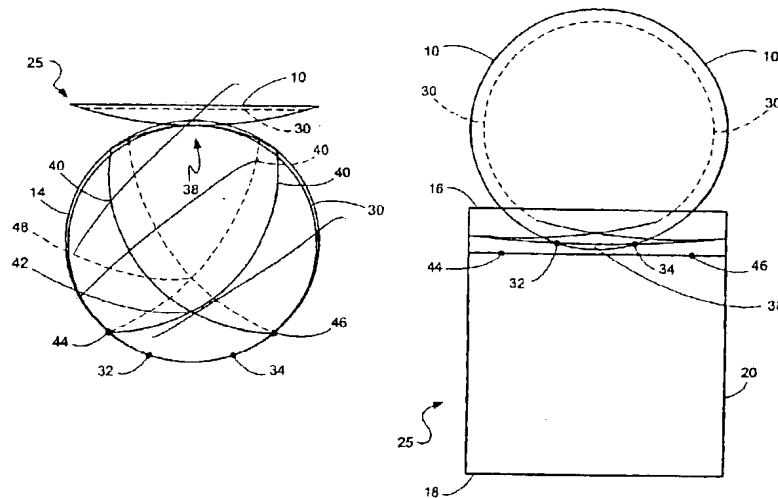
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- (74) Agents: FÜCHSLE, Klaus et al.; Hoffmann.Eitle, Ara-
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- (88) Date of publication of the international search report:
12 December 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STENT WITH VALVE



(57) Abstract: A heart valve stent (25) and method for treating a patient with a fluid circulatory system defect is provided. The stent has a metal stent body (14), which is expandable from a compressed state to an expanded state. The stent body in the expanded state has a hollow structure and a leaflet (10) attached thereto with the leaflet movable from an open to a closed position to allow unidirectional fluid circulation and to prevent non-unidirectional fluid circulation through the hollow structure, which is translucent to magnetic resonance imaging signals by not producing eddy currents in response thereto.

WO 02/047575 A3

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/EP 01/14822

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 200 03 874 U (FRAUNHOFER-GESELLSCHAFT ZUR FÖRDERUNG DER ANGEWENDTEN FORSCHUNG) 25 May 2000 (2000-05-25) page 6, line 5 -page 7, line 30; figure 1	1,2,4-10
Y	WO 95 05133 A (COUETIL JEAN PAUL) 23 February 1995 (1995-02-23) abstract page 5, line 3 - line 25 page 6, line 10 - line 12; figures	1,2,4-10
X	EP 1 057 460 A (NUMED INC) 6 December 2000 (2000-12-06) cited in the application	11,12, 15-17, 19-21, 23,24
Y	the whole document	9,10,13, 14,22

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

30 September 2002

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/EP 01/14822

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 57599 A (CAMILLI SANTE) 23 December 1998 (1998-12-23)	13,14,22
A	abstract page 6, line 1 - line 13 page 7, line 10 - line 20 ---	2,4,6
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 01/14822

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 25
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/EP 01/14822

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